UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,506	10/03/2005	Mao-Hsiung Yen	U 015722-1	8980

140 7590 10/26/2009

LADAS & PARRY LLP
26 WEST 61ST STREET
NEW YORK, NY 10023

EXAMINER
PESELEV, ELLI

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
10/26/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

nyuspatactions@ladas.com

Office Action Summary	Application No.	Applicant(s)	
	10/531,506	YEN ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,10-14,18,31,33,39,44-46,52-54 and 60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *11* is/are allowed.

6)☒ Claim(s) *1, 10, 12-18, 31, 39, 44-46, 52-53 and 60* is/are rejected.

7)☒ Claim(s) *4 and 33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 4 and 33 are objected to because of the following informalities: Claims 4 and 33 are duplicates. Appropriate correction is required.

Claims 14, 18, 31, 39, 44-46, 52-54 and 60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the invention without undue experimentation.

(A) The breadth of the claims.

Claim 14 is directed to the treatment of rheumatoid arthritis, Crohn's disease, organ failure or pulmonary fibrosis.

Claims 18 and 60 are directed to the treatment of liver damage, lung damage and/or kidney damage.

Claims 31, 44, 45 and 53 are directed to the treatment of diseases associated with the overproduction of TNF-alpha, overproduction of superoxide anion radical, liver damage and/or kidney damage.

Claims, 46, 52 and 54 are directed to the treatment of diseases associated with the overproduction of TNF-alpha, liver damage, lung damage and/or kidney damage.

On page 24 of the specification it is stated that diseases associated with the overproduction of TNF-alpha include, but are not limited to arthritis, rheumatoid arthritis, Crohn's diseases, ulcerative colitis, insulin resistance, multiple sclerosis, organ failure failure, pulmonary fibrosis and atherosclerosis. Also, it is stated that the diseases associated with overproduction of superoxide anion radical include, but are not limited to, Alzheimer's disease, Parkinson's disease, aging, cancer, myocardial infraction, atherosclerosis, autoimmune disease, radiation injury, emphysema, sunburn, joint disease and oxidative stress. Further, it is stated that organ damage may result from causes which include, but are not limited to, cancer, infections, exposure to environmental toxins or allergens, exposure to chemical substances such as drugs and alcohol, and conditions such as hepatitis, cirrhosis, diabetes, hypertension, glomerulonephritis, kidney stones, polycystic kidney disease, pneumonia, tuberculosis, emphysema, bronchitis and asthma.

(B) The level of predictability in the art.

The activity of various flavones is unpredictable. For, example, Lee et al (WO 01/30342) disclose in Example 2 that of the eight flavone compounds tested, only oroxylin A inhibited LPS- induced COX-2 gene expression in both protein and mRNA levels. Further, there is a good reason to doubt that a compound can be useful in treating organ damage resulting from such unrelated conditions, as for example, cancer, infections, diabetes, exposure to alcohol and asthma,

(C) The existence of working examples.

The working example directed to the in vitro effect of baicalein on plasma THF-alpha, superoxide anion, nitrate and iNOS. However, there is no correlation between the levels of THF-alpha, superoxide anion, plasma nitrate and iNOS and the treatment of any diseases. Further, the present claims are not directed to baicalein. Therefore, there are no working examples showing any activity of the claimed compounds.

(D) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Because there is no way to predict a priori which specific compounds encompassed by the present claims will be useful for treating which specific disease or condition, it would take an enormous amount of experimentation to determine the effectiveness of the claimed methods.

Applicant's arguments filed July 24, 2009 have been fully considered but they are not persuasive.

Applicant contends that those skilled in the art have an understanding of the nature of conditions encompassed by the present claims. This argument has not been found persuasive. The literature submitted and the test data submitted are limited to a protocol of TNF-alpha inhibition assay and to the activity of various compounds directed to the TNF-alpha in vitro inhibition. No evidence has been provided related to the correlation of said inhibition in vitro and the treatment of any conditions encompassed by the present claims in vivo.

Claims 1, 12-14, 18, 31, 44, 45 and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s)

contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The terminology "R1 and R2 together with the atoms to which they are bound form a methylenedioxy group" and "R2 and R3 together with the atoms to which they are bound form a methylenedioxy group" is not disclosed in the specification as originally filed.

Applicant's arguments filed July 24, 2009 been fully considered but they are not persuasive.

Applicant contends that the last two compounds described on page 36 show R1 and R2 forming a methylenedioxy group. This argument has not been persuasive. The compounds shown on page 35 of the specification are not encompassed by the present claims. Further, there is no example of compounds wherein R2 and R3 form a methylenedioxy group.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 10, 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Cassels et al (U.S. Patent No. 5,756,538).

Cassels et al disclose the claimed compounds wherein R1, R2, and R3 are each independently H or lower alkyl and X1 is benzyl (column 1, lines 45-63). A person having ordinary skill in the art at the time the claimed invention was made would have envisaged the claimed from the reference's disclosure.

Applicant's arguments filed July 24, 2009 have been fully considered but they are not persuasive.

The reference's disclosure is not limited to specific embodiments. Cassels et al disclose a limited number of species in column 1, which encompass the presently claimed compounds. Note, that the rejected claims are not limited to specific species. A person having ordinary skill in the art at the time the claimed invention was made would have envisaged the claimed genus from the reference's genus.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev
/Elli Peselev/
Primary Examiner, Art Unit 1623